DEPARTMENT OF STATE REVENUE

REVENUE RULING ST 98-02

February 6, 1998

NOTICE: Under IC 4-22-7-7, this document is required to be published in the Indiana Register and is effective on its date of publication. It shall remain in effect until the date it is superseded or deleted by the publication of a new document in the Indiana Register. The publication of this document will provide the general public with information about the Department's official position concerning a specific issue.

ISSUE

Sales/Use Tax - Sale of Coronary Stent Catheters and Related Products

Authority: IC 6-2.5-5-18, Rule 45 IAC 2.2-5-27, IC 6-2.5-8-8

The taxpayer requests the Department to rule on the application of sales/use tax to the sale of coronary stent catheters and related products.

STATEMENT OF FACTS

The taxpayer is a distributor of coronary stent catheters and their related products. The taxpayer purchases the coronary stent catheters and their related products from a sister corporation. The sister corporation manufactures medical products used in the treatment of coronary artery disease through a procedure called coronary stenting. Its products are as follows:

(1) Coronary stent catheter
(2) Coronary guide wires
(3) Coronary guiding catheters
(4) Accessories

Indeflator inflation device
Angioject (syringe)
Hemostatic valve
Guide wire introducer
Torque device
Priority Pack accessory kit (includes 1 Indeflator inflation device, 1 hemostatic valve, 1 guide wire introducer and 1 torque device)
Guide wire accessory kit (includes 1 hemostatic value, 1 guide wire introducer and 1 torque device).

All of the sister corporation's products can only be used or dispensed by a physician on a physician's written prescription. In addition, all of the products contain the label stating that federal (U.S.A.) law restricts the use of the products to physicians or to use under the direction of a physician.

Balloon angioplasty is a medical procedure used to widen narrowings in the coronary artery without surgery. Narrowings are caused by a gradual build-up of fat (cholesterol) or calcium deposits within the artery walls.

The major challenge to angioplasty is clinical restenosis, or the renarrowing of the blood vessel following the angioplasty procedure. Clinical restenosis can manifest as either the collapse of the artery as a result of the weakening of the artery walls following angioplasty or as the reoccurrence of the cholesterol or calcium deposits within the artery wall. Clinical restenosis may occur immediately following the angioplasty procedure, or anytime over the next several months or years. Treatment of clinical restenosis generally requires a subsequent angioplasty procedure or, in more severe instances, surgery. Clinical restenosis occurs in approximately twenty to thirty percent of patients undergoing angioplasty procedures.

Coronary stenting is a technique with mechanically props open the artery through implementation of a small, latticed stainless steel tube at the site of the narrowing. The stainless steel tube - the stent - is premounted on a coronary angioplasty balloon catheter. As the balloon catheter is inflated during angioplasty, the stent expands and is compressed against the artery walls. When the balloon is deflated, the expanded stent remains implanted in the artery. This technique of mechanically propping open the artery with the stent greatly reduces the rate of clinical restenosis.

The patient is awake during coronary stenting. A local anesthetic is injected where the catheter is inserted, the skin is punctured with a hollow gauge needle to gain access to the artery. Once the artery is located, an introducer sheath is inserted. This sheath provides a direct and smooth pathway for the catheter to enter the artery.

A coronary guiding catheter is inserted into the introducer sheath. The coronary guiding catheter is advanced to the part of the aorta where the coronary arteries branch off to the heart. A hemostatic value, which controls the flow of blood through the artery, is attached to the end of the coronary guiding catheter to allow for the insertion of coronary

catheters. Note that a coronary guiding catheter is a conduit for the coronary guide wire and the coronary catheters to access the coronary artery. Coronary catheters rely on the support provided by the coronary guiding catheter.

A manifold device is also fastened to the guiding catheter. The manifold has three valves. One is used to monitor the patient's blood pressure, another is used to inject contrast medium (x-ray dye) and the other is used for a flushing solution. An angioject syringe is used at the end of the manifold to inject contrast medium so the physician can visualize the coronary arteries.

A coronary guide wire is loaded into the coronary guiding catheter through the use of a guide wire introducer, and advanced to the cardiac vessel just past the narrowing. Coronary guide wires are used to support the coronary catheters as they are advanced across the artery narrowing. A torque device is placed on the end of the coronary guide wire and is used to steer the coronary guide wire to the artery until its tip is beyond the narrowing.

A coronary stent catheter is inserted at the distal end of the coronary guide wire and is advanced across the narrowing over the coronary guide wire through the guiding catheter. The balloon catheter that holds the stent has gold markers at the proximal and distal ends of the balloon. These markers are visible on an x-ray monitor and allow the physician to properly position the catheter across the narrowing. Once in position, the balloon is inflated with contrast medium (x-ray dye) using an Indeflator inflation device. The Indeflator inflation device is specifically designed for the purpose of inflating the balloon. The Indeflator inflation device hooks up to a side port valve, outside the body on the coronary stent catheter. It also measures and monitors the amount of pressure required to inflate the balloon. Inflation of the balloon compresses the plaque against the wall of the artery and causes the stent to expand and press against the vessel wall. When the balloon is deflated, the expanded stent remains as a reinforcement for the artery wall.

Depending upon the condition and position of the narrowing and the preference of the physician, the stenting procedure may be preceded and/or followed with separate angioplasty procedures. These procedures either predilate the lesion allowing better access for the coronary stent catheter or post dilate the lesion allowing the physician to ensure proper deployment of the stent.

After the plaque has been compressed and the artery has been opened sufficiently, the deflated coronary stent catheter, coronary guide wire and coronary guiding catheter are removed and disposed. The stent remains permanently in the body, holding the artery open and thus improving blood flow.

Questions Submitted by the Taxpayer for Departmental Rulings

1. Are the following products exempt from Indiana sales tax?
    (a) Coronary stent catheter
    (b) Coronary guide wires
    (c) Coronary guiding catheters
    (d) Accessories
        (1) Indeflator inflation device
        (2) Angioject (syringe)
        (3) Hemostatic valve
        (4) Guide wire introducer
        (5) Torque device
        (6) Priority Pack accessory kit (includes 1 Indeflator inflation device, 1 hemostatic valve, 1 guide wire introducer and 1 torque device)
        (7) Guide wire accessory kit (includes 1 hemostatic value, 1 guide wire introducer and 1 torque device).

DEPARTMENTAL RESPONSE

IC 6-2.5-5-18 provides that the sale of medical equipment, supplies and devices is exempt from sales/use tax if the sale is prescribed by a person licensed to issue the prescription. Rule 45 IAC 2.2-5-27 states that "prescribed" means a certification in writing, by a person licensed or registered to fit and/or dispense medical equipment, supplies and devices, that the use of the medical equipment, supplies and devices is necessary to the purchaser in order to correct or alleviate a condition brought about by injury to, malfunction of, or removal of a portion of the purchaser's body. Further, a restriction on medical equipment, supplies and devices by federal (U.S.A.) law that limits the use of such medical equipment, supplies and devices to physicians or to use under the direction of a physician is tantamount to a physician prescribing the medical equipment, supplies and devices.

The Department rules that the sale by the taxpayer of the above products that are used in an invasive surgical procedure that is necessary to correct or alleviate a condition brought about by injury to, malfunction of, or removal of a portion of a patient's body and that are prescribed by a physician (and/or restricted to use by a physician or to use under a physician's direction) is not subject to sales/use tax.

2. If any of the above products are determined taxable, can they be purchased for resale if the Indiana hospitals

separately itemize these products on the patient's bill?

DEPARTMENTAL RESPONSE

This question is not applicable.

3. Can the taxpayer accept a resale certificate, in good faith, from a hospital purchasing taxable medical products, and separately billing such taxable goods on patient invoices, if the taxpayer does not have the knowledge whether the hospital actually taxes such billable products to patients?

DEPARTMENTAL RESPONSE

IC 6-2.5-8-8 provides that a retail merchant is required to collect sales/use tax on the sale of tangible personal property unless the retail merchant accepts a proper Indiana exemption certificate, i.e., on forms and completed in the manner prescribed by the Department, from the purchaser. Upon accepting a proper Indiana exemption certificate from a purchaser, the retail merchant has no duty to collect or remit sales/use tax on that purchase. Further, the retail merchant is not responsible for verifying that the tangible personal property purchased will be used in an exempt manner.

The Department rules that the taxpayer is required to either collect sales/use tax on the sale of taxable medical products or receive a proper Indiana exemption certificate from the purchaser.

4. How would the state tax the stents if they are purchased separately from the coronary angioplasty balloon catheter, i.e., the doctors would manually mount the stents on the catheter?

DEPARTMENTAL RESPONSE

Pursuant to IC 6-2.5-5-18 and Rule 45 IAC 2.2-5-27, the Department rules that the sale of stents separately from the coronary angioplasty balloon catheter is not subject to sales/use tax.

CAVEAT

This ruling is issued to the taxpayer requesting it on the assumption that the taxpayer's facts and circumstances, as stated herein, are correct. If the facts and circumstances given are not correct, or if they change, then the taxpayer requesting this ruling may not rely on it. However, other taxpayers with substantially identical factual situations may rely on this ruling for informational purposes in preparing returns and making tax decisions. If a taxpayer relies on this ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material respect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that subsequent to the publication of this ruling, a change in a statute, a regulation, or case law could void the ruling. If this occurs, the ruling will not afford the taxpayer any protection.